K123136

MAR 7 2013

510(k) Summary

Submitter **807.92(a)(1)**	**Nathan Cross CEO** **Genesis Health Technologies, Inc.** 1640 McCracken Blvd. Paducah, KY 42001 888-263-0003 ncross@genesishealthcaretechnologies.com
Contact Person	Kathleen Johnson Medical Device Approvals, Inc. PO Box 2042 Fairfield, IA 52556 641-472-0775 kathleen@mdapprovals.com
Date Prepared	December 12, 2012
Trade Name 807.92(a)(2)	Genesis Health Record System (GHRS)
Common Name	Data Management System
Classification Name 807.92(a)(2)	21 CFR 862.2100 Calculator/data processing module for clinical use Class II regulated as an accessory to Blood Glucose Meters
Classification Panel	Clinical Chemistry 71
Product Code	NBW-System test Blood Glucose Over the Counter JQP-Calculator/Data Processing Module for Clinical Use
Predicate Device 807.92(a)(3)	ISENS PC care blood Glucose data Management Software K100937
Device Description 807.92(a)(4) Operating Principle	1. The Genesis Health Record System (GHRS) is an internet browser based data management system for use with the Genesis Health Technologies Blood Glucose Meter Cleared under K121224. 2. The GHRS data management system allows patients to wirelessly transmit the results of glucose testing including the test result, date and time from the blood glucose meter via a CDMA module in the blood glucose meter over the Verizon wireless network, to a secure central database. The results are then stored on a secure central database and can be accessed through the internet by patients and/ or authorized healthcare professionals, on a personal computer running any operating system with access to the internet. The user can review and evaluate results of blood glucose tests and related information to aid in the management of diabetic patients.

	Results can be displayed on the computer in the form of a Log Book report showing test results from a specified date range, a graphical display of the patient's results and a trending report showing within target and out of target percentages.
System Requirements	3. A current internet browser and internet access are required to reach the MyGHR website. No other programs or applications need to be installed on a computer terminal. No cables are required. The User goes to the MyGHR website and sets up their account.
General Functions	The data is accessed via an internet browser and a secure login portal requiring a user name and password. The Software System consists of three levels of access or environments of use: 1- The MyGHR System for Home use by the patient This portal is for the patient to access their results as sent from the meter, analyze results as compared to targets and generate charts and graphs to show trends. 2- The MyGHR Plus for Professional use by the healthcare professional allows an authorized healthcare professional to access data for patients and analyze results in terms of meeting target levels and also to generate graphs and charts to visualize results over a designated time period. 3- The GHR-ADMIN is for technical support only and accessed only by GHRS employees only. An on-line tutorial guides the user through the setup and use process. Patients enter information such as a target blood glucose range. Graphs and tables that are displayed can be printed. Alerts can be sent via text message or email for test results if desired.
Intended Use	The Genesis Health Record System is intended to be used as an accessory to the Genesis Health Technologies Blood Glucose Meter, Model TD-4123 to assist in the review and evaluation of blood glucose test results and related information to aid in diabetes management. The System is not intended to provide automated treatment guidance or decisions.
Indications for Use	It is indicated for use by adult diabetic patients for use in the home and by healthcare professionals in the professional

	setting. The System is not indicated for the diagnosis or screening of diabetes.
Technological Characteristics	The GHRS uses wireless technology incorporating a CDMA module into the meter to transmit readings over a wireless network to a secure central server for review and analysis. The MyGHR website portal is accessed via internet browser.
Non-Clinical Testing	Software verification and validation has been performed and demonstrated safety, repeatability and effectiveness of the GHRS remote database and substantial equivalency to the predicate devices.
Bench Testing	The following Verification and Validation Tests are included in this submission: • Validation of the logbook functionality, including proper date selection/filtering, proper display of all Reading Types, Accuracy of display data for all reading types and verification of all calculations. Found in GHRS V & V Test Plan 2.21.4 pgs.: 13-17. • Validation of the Test History Chart, including proper date selection/filtering, proper display of all Reading Types, ACCURACY of display data for ALL reading types and verification of calculations. Found in GHRS V & V Test Plan 2.21.4 pgs.: 17-18. • Validation of the logbook functionality for the Target Range Chart, including proper date selection/filtering, proper display of all Reading Types, ACCURACY of display data for ALL reading types, verification of calculations. Found in GHRS V & V Test Plan 2.21.4 pgs.: 19-20. • Validation of accuracy of all mathematical calculations including summary data, and statistics used by the system. Found in GHRS V & V Test Plan 2.21.5 All pages. • Validation of data accuracy from meter to server, including ALL upload scenarios including: automatic, delayed, and multiple for all reading types including before meals, after meals, general and all reading ranges including Low, in range, and High. Found in GHRS V & V Test Plan 2,21,6 All pages. • Verification of the device functionality related to data upload and the flight safe switch mode. Found in GHT BGM V & V Test Plan 1.13.1.

Human Factors Study	A Human Factors study was performed with 25 test Home Use participants, 25 meters, and 4 Healthcare Professionals all with average computer skills. The study evaluated the entire system setup as well as data download and 100% accuracy of the transmitted data. An analysis of user completed tasks was performed. A user evaluation analysis incorporating a 5 point Likert Scale with measures ranging from Strongly Disagree to Strongly Agree was used. The study was also used to confirm 100% accuracy for data transmission from the meter to the data base and data integrity when analyzed in the intended use environment.	
Clinical Testing	N/A	
Substantial Equivalence Information		
Feature	**Candidate Device: GHRS**	**Predicate Device: PC Care by i-SENS K100937**
Intended Use	The Genesis Health Record System is an accessory to blood glucose meters to assist in the review and evaluation of blood glucose test results and related information to aid in diabetes management. It is indicated for use by adult diabetic patients for use in the home and by healthcare professionals in the professional setting. The System is not intended to provide automated treatment guidance or decisions. The System is not indicated for the diagnosis or screening of diabetes.	The PC care™ Blood Glucose Data Management Software is a PC-based software intended for use in the home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for an effective diabetes management program. The PC care™ Blood Glucose Data Management Software connects to an i-SENS blood glucose meter, which comes with a PC care USB cable. The PC care™ Blood Glucose Data Management Software allows the user to download blood glucose readings automatically from the meter to the PC.
Major Features of Device		
Transfer data from a blood glucose meter to a database	Yes, automatically, from device to a remote database wirelessly over a secure cellular network using CDMA technology.	Yes, automatically from device to PC via a special USB cable
Data can be analyzed by	Yes, Logbook, Logbook	Yes Logbook, Logbook

user to display trends in graph form. Multiple types of reports can be displayed	summary, Test history in graph formats, Trends over specified date range	summary, Test history in graph formats, Trends over specified date range
Data is stored in a Database	Yes in a remote server	Yes on the local PC
Results and reports can be shared with others	Yes, authorized users can log on to MYGHR website and view results	Yes, reports can be attached to email or printed out.
Parameters can be customized	Yes target ranges, dates various health parameters	Yes target ranges, dates, various health parameters
Software Use Indications	Home Use (patient) and Professional Use(Healthcare Professional)	Single or Multiple user settings
Installation of Program	Not required Site is internet based and accessed through a web browser	Installed using a CD
Computer System Requirements	Device using Windows, Mac, iPhone, Android or similar OS, with one of the following approved browsers installed: Internet Explorer 9 Mozilla Firefox 12 Apple iOS 5 Apple Safari 5.1 Google Chrome 19 Android Internet Browser 2.3	CPU: Minimum 300 MHZ Intel Pentium 2 Windows 95, Windows 98, Windows ME, Windows 2000, Windows XP, Windows Vista and Windows 7 Minimum free hard disk space: 60MB RAM 128MB or higher USB port required PC Care USB Cable Mouse and Keyboard Video monitor with 1024x768 pixel screen minimum and 256 colors CD-Rom drive optional printer
Access to DMS	Accessed via internet on any PC with internet connection and approved browser	From personal computer via program
Indication time of test	Yes (One of: Normal, Before Meal, After Meal, Control Solution)	Yes (One of: Normal, Before Meal, After Meal, Control Solution)
Technical Support	Yes	Yes
User Manual	Yes accessed online	Yes on program installation CD

Summary of Technological Differences	1. The candidate device uses wireless technology to allow the user to instantly upload test results from the meter to the remote database. The predicate requires the user to connect the meter to a PC via a USB cable to upload results stored on a local hard drive. 2. The candidate device allows patient results to be accessed on any computer with internet access and a current internet browser. The predicate device requires the patient to access their results from the PC where the program is installed. 3. The candidate device allows authorized healthcare professionals to directly access and analyze patient results via an internet portal and secure login screen The predicate device requires patients to email or print out and send reports to their healthcare professionals for review.
Summary of similarities	1. Both devices allow patients to upload their test results from the BGM to a database 2. Both devices allow for analysis of results in table, chart and graph form. 3. Both devices are intended to assist patients and healthcare providers in the management of diabetes.
Conclusion	The candidate device has the same intended use as the predicate device. Bench testing has validated the accuracy and reliability of the device. A Human Factors study has demonstrated the usability of the device by its intended user population. Therefore, the Genesis Health Record System is found to be substantially equivalent to the predicate device in both intended use and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2013

Genesis Health Technologies, LLC
c/o Kathleen Johnson, President
Medical Device Approvals, Inc.
P. O. Box 2042
Fairfield, IA 52556

Re: k123136
Trade/Device Name: Genesis Health Record System (GHRS)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: January 22, 2013
Received: January 30, 2013

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123136

Device Name: Genesis Health Record System

Indications for Use: The Genesis Health Record System is an accessory to the Genesis Health Technologies Blood Glucose Meter, Model TD-4123 to assist in the review and evaluation of blood glucose test results and related information to aid in diabetes management. It is indicated for use by adult diabetic patients for use in the home and by healthcare professionals in the professional setting. The System is not intended to provide automated treatment guidance or decisions. The System is not indicated for the diagnosis or screening of diabetes.

Prescription Use __X__ And/Or Over the Counter Use __X__
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

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